

# EXHIBIT I

STATE OF INDIANA  
COUNTY OF MARION

SS:

MARION COUNTY SUPERIOR COURT

CAUSE NO.

49D02 1601 CT 001221

MARY LOU RETTON-KELLEY,

Plaintiff,

v.

BIOMET ORTHOPEDICS, LLC,  
BIOMET, INC., and  
ZIMMER BIOMET, LLC,

Defendants.

Complaint for Damages

**FILED**

15

JAN 12 2016

*Myla A. Eldridge*  
CLERK OF THE MARION CIRCUIT COURT

This is a product liability case involving a defective hip implant system. Plaintiff Mary Lou Retton-Kelley, had a Biomet M2a Magnum Metal-on-Metal Hip System ("M2a Magnum Hip System") implanted each hip at separate times. The M2a Magnum Hip System is a metal-on-metal hip implant that causes excessive amounts of cobalt and chromium to corrode and wear from the surfaces of the acetabular cup, the femoral head, and the taper sleeve, which in turn causes complications from the excess metal in the blood, among other complications.

### **PARTIES**

1. Plaintiff Mary Lou Retton-Kelley is a resident of the State of Texas and resides in Harris County, Texas.

2. On information and belief, Defendant Biomet Orthopedics, LLC is a limited liability corporation, organized and existing under the laws of the state of Indiana, with its primary place of business in Warsaw, Indiana. Biomet Orthopedics, LLC designed, manufactured, marketed, promoted, and sold the M2a Magnum Hip System, which is the subject of this lawsuit.

3. On information and belief, Defendant Biomet, Inc. is a corporation organized and existing under the laws of the state of Indiana with its primary place of business in Warsaw, Indiana. Biomet, Inc. designed, manufactured, marketed, promoted, and sold the M2a Magnum Hip System that is the subject of this lawsuit.

4. Zimmer Biomet, LLC is the successor in interest to Biomet after the merger of Zimmer and Biomet in 2015. Zimmer Biomet, LLC is a domestic limited liability company in Indiana.

5. At all relevant times, Biomet Orthopedics, LLC, Zimmer Biomet, LLC, and Biomet, Inc. were the representatives, agents, employees, joint venture, or alter egos of each other. Defendants were within the scope of authority when performing the actions or inactions complained of in this lawsuit. Specifically, each Defendant was but an instrumentality or conduit of the other in the prosecution of a single venture; namely the design, promotion, and sale of the M2a Magnum Hip System.

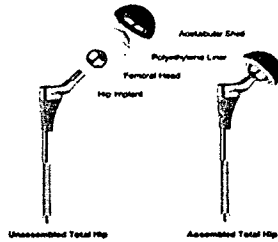
6. Biomet Orthopedics, LLC, Zimmer Biomet LLC, and Biomet, Inc. are collectively referred to as "Biomet."

### **JURISDICTION**

7. The Court has original jurisdiction in this civil action because Defendants are all citizens and residents of the state of Indiana. Pursuant to 28 U.S.C. §1441(b), this matter is not removable to federal court.

## **FACTUAL BACKGROUND**

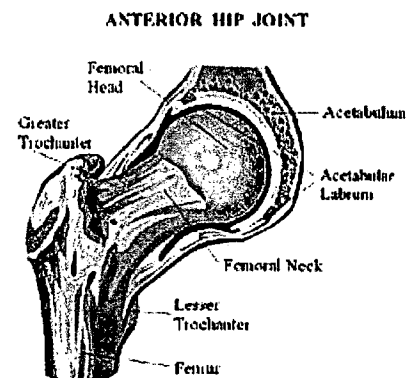
### **A. The M2a Magnum Hip System Is Defective and Was Not Adequately Tested.**



8. The hip joint is where the femur connects to the pelvis. The joint is comprised of the femoral head (a ball-like structure at the very top of the femur) rotating within the acetabulum (a cup-like structure at the bottom of the pelvis). In a healthy hip, both the femur and the acetabulum are strong and the rotation of the bones against each other, and cartilage and fluids cushion and lubricate the joint.

9. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. A typical total hip replacement system consists of four separate components: (1) a femoral stem; (2) a femoral head; (3) a plastic (polyethylene) liner; and (4) an acetabular shell. After the surgeon hollows out a patient's femur bond, the femoral is implanted. The femoral head is a metal ball fixed on top of the femoral stem. The femoral head forms the hip joint when it is place inside the polyethylene liner and acetabular shell.

10. While most hip replacements use a polyethylene *plastic* acetabular liner, Biomet's M2a Magnum Hip System has a critical difference: it is a mono-block system, which does not have an acetabular liner. Without such a liner, the M2a Magnum Hip System forces metal to rub against metal with the full weight and pressure of the human body. Biomet's



defective design for the M2a Magnum Hip System has forced hundreds of patients - including Mary Lou Retton-Kelley - to undergo surgeries to repair or replace these hip implants.

11. The M2a Magnum Hip System suffers from a design and/or manufacturing defect that causes excessive amounts of cobalt and chromium to wear and corrode from the surface of the acetabular cup, from the femoral head, and from the taper adapter. These cobalt and chromium fragments prompt the body to react by rejecting the hip implant. This rejection often manifests with symptoms of pain, loosening of the hip implant, dislocation, squeaking, and popping sounds. Inside the hip joint, the metal reaction often causes fluids to accumulate; resulting in the death of soft tissue and bone.

12. Biomet did not sufficiently test the design of the M2a Magnum Hip System, and the FDA never approved that design as being safe or effective for the products intended purpose.

13. On numerous occasions, Biomet met with orthopedic surgeons, including Plaintiff's orthopedic surgeon, to promote the M2a Magnum Hip Implant. A Biomet representative was present at some or all of these meetings. During these meetings, Biomet assured the orthopedic surgeons, including Plaintiff's orthopedic surgeon, that the M2a Magnum Hip System was safe, was the best product on the market, had an excellent track record and had a low and acceptable failure rate. Biomet continued to "defend" the M2a Magnum Hip Implant even after they became aware of numerous and serious complications with the M2a Magnum Hip System. Biomet did not reveal (and instead concealed) their knowledge of numerous and serious complications and other "bad data" during their meetings with orthopedic surgeons, including Plaintiff's orthopedic surgeon.

**B. Biomet Sold the M2a Magnum Hip Implant to Plaintiff After Knowing It Was Defective, That It Had Injured Others, and That It Would Injure Plaintiff.**

14. Biomet launched the M2a Magnum Hip System in 2000 and received complaints soon after that launch. For example, in August 2004, Biomet received a

complaint that a patient had to undergo surgery to remove and replace an M2a Magnum Hip System because it became loose after only 3 years.

15. Biomet would go on to receive hundreds of similar complaints reporting that the M2a Magnum Hip System failed, and that the failure forced patients to undergo painful and risky surgeries to remove and replace the failed hip component. To date, the FDA received more than 350 reports of adverse events associated with the M2a Magnum Hip System.

16. Between 2006 and the end of 2011, more than 200 reports had been filed with the FDA reporting adverse events associated with the M2a Magnum Hip System. Consequently, Biomet was fully aware that the M2a Magnum Hip System was defective and that defect already injured hundreds of patients. Based on this information, Biomet should have ensured that patients and surgeons were educated as to the true nature and extent of the risks associated with the M2a Magnum Hip System so that surgeons could make informed decisions as to the treatment options available.

17. Biomet continued to sell the defective M2a Magnum Hip System, despite knowing that the M2a Magnum Hip System was defective, failed hundreds of times, and caused hundreds of patients to undergo the agony of another surgery. Biomet actively concealed the known defects and risks associated with the M2a Magnum Hip System from the doctors and patients, including Plaintiff and Plaintiff's doctor, and misrepresented that the M2a Magnum Hip System was a safe and effective medical device.

18. As Biomet received numerous complaints regarding the M2a Magnum Hip, it continued to actively promote, market, and defend the defective products. For example, Biomet published marketing brochures touting the safety and durability of metal-on-metal

implants generally and the M2a Magnum Hip System specifically. Biomet gave these brochures to doctors around the world, including Plaintiff's orthopedic surgeon, to encourage them to use the M2a Magnum Hip System.

19. Despite knowing that the M2a Magnum Hip System was defective, Biomet made false representations about specific design elements of the M2a Magnum Hip System. Biomet claimed that the M2a Magnum Hip System was safer than other hip implants on the market. For example, Biomet said:

“The M2a Magnum™ Large Metal Articulation System offers optimal joint mechanic restoration and ultra-low wear rates *in vivo*.”

“Many studies conducted over the last several decades have shown no definitive correlation of negative health issues to ion levels exhibited from metal-on-metal implants.”

**C. Plaintiff's Injuries.**

20. Plaintiff underwent surgery to implant the M2a Magnum Hip System on her left hip on or about 2005 by Dr. Bryan Parsley. Plaintiff had an additional implant on her right hip on or about 2011 by Dr. Bryan Parsley.

21. After undergoing bilateral implants of Biomet's M2a Magnum Hip System, Plaintiff suffered personal and economic injuries because of Biomet's implants. These damages include, but are not limited to: severe past and future pain and suffering, excessive levels of chromium and cobalt in her blood, fluid in and around the left hip implant, disability, physical impairment, disfigurement, severe past and future emotional distress and mental anguish, inconvenience, aggravation of a pre-existing condition, loss of the capacity for the enjoyment of life, past and future medical and other expenses and loss of earning capacity. Plaintiff's injuries and losses are permanent in nature and Plaintiff will continue to suffer such losses in the future.

22. On or about June 29, 2015, Plaintiff underwent revision surgery of her left hip implant due to injuries from the defective M2a Magnum Hip System. Revision surgery for her right hip is planned, but not yet scheduled.

23. Plaintiff suffered serious bodily injury and harm as a direct and proximate result of using Defendants' M2a Magnum Hip System.

24. Plaintiff incurred, and continues to incur, medical expenses to treat her injuries and conditions as a direct and proximate result of using Defendants' M2a Magnum Hip System.

25. Though their action or inactions, Defendants directly and proximately caused Plaintiff's injuries.

26. Plaintiff could not have known of the excessive levels of chromium and cobalt in her blood until having her blood drawn, tests performed, and having a healthcare provider communicate those results to her.

27. As a result of the injuries Plaintiff sustained, she is entitled to recover compensatory damages for pain and suffering and emotional distress and for economic loss as well as punitive damages.

28. As discussed further below, Defendants' fraudulent concealment tolled the running of any statute of limitations. Defendants failed to disclose risks associated with the implantation of the M2a Magnum Hip System including: the risk of chromium and cobalt ions being released into the body, the risk of tissue death associated with the release of chromium and cobalt ions, the risk of bone death associated with the release of chromium



and cobalt ions, the need for additional surgeries from damages associated with the release of chromium and cobalt ions, and loosening of the implant. Additionally, on information and belief, between 2006 and 2013, Defendants actively represented to Plaintiff that their implant produced drastically fewer metal ions than other comparable implants, that Defendants' implant was safer than comparable implants in part due to the release of fewer metal ions, and that the implant was safe for use. Plaintiff and her physician(s) were unaware, and could not have learned through reasonable diligence, that Plaintiff was exposed to those risks, that those risks caused Plaintiff's injuries, and that those risks were the direct and proximate result of Defendants' acts and omissions. Only upon having her blood drawn on or about January 22, 2014 did Plaintiff learn of her heightened levels of chromium and cobalt. Despite knowing that its implants were "ticking bombs" regarding metal release into humans, Defendants never told Plaintiff, and Plaintiff, in reliance, delayed seeking legal or medical help.

## **CAUSES OF ACTION**

### **COUNT I**

#### **PRODUCTS LIABILITY - STRICT LIABILITY**

**(Indiana Products Liability Act, Ind. Code §34-20, *et seq.*)**

29. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

30. At all relevant times, Defendants were engaged in the development, testing, manufacturing, marketing, and sales of M2a Magnum Hip System. Defendants knew the M2a Magnum Hip System was for hip replacement surgeries. Defendants designed, manufactured, marketed, and sold the M2a Magnum Hip System to medical professionals and their patients.

31. For purposes of the Indiana Products Liability Act, Plaintiff was a consumer of the M2a Magnum Hip System because Plaintiff purchased the product, had the product

implanted, used the product, and possessed the product until its partial replacement in June 29, 2015.

32. The M2a Magnum Hip System, as designed, manufactured, marketed, and sold by Defendants, reached Plaintiff without substantial change in its condition. Plaintiff used the product in a reasonably foreseeable and intended manner.

33. The M2a Magnum Hip System was “defective” and “unreasonably dangerous” when it entered the stream of commerce and was implanted into Plaintiff, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. Plaintiff never had reason to believe that M2a Magnum Hip System was in an unsuitable condition for its intended use among patients.

34. Defendants knew the product could harm those implanted with it, and Plaintiff is part of that class of persons.

35. Use of the M2a Magnum Hip System as intended resulted in Plaintiff’s injuries.

36. Plaintiff was not able to discover, nor could she have discovered through the exercise of reasonable care, the harmful nature of the M2a Magnum Hip System. Plaintiff could not have known that Defendants designed, developed, and manufactured the M2a Magnum Hip System in such a way as to increase the risk of harm or injury to recipients.

37. Defendants’ wrongful conduct caused Plaintiff to sustain and continue to sustain severe and debilitating injuries. These injuries include, but are not limited to, economic loss cost of medical care, rehabilitation, lost income, instability, loss of balance, immobility, pain, and suffering. These damages entitle Plaintiff to compensatory damages equitable damages in an amount determined at trial.

38. Plaintiff demands judgment against Defendants for compensatory damages, punitive damages, interest, costs of suit, attorneys' fees, and all other relief the Court deems proper.

**COUNT II**  
**PRODUCTS LIABILITY – DEFECTIVE DESIGN**  
**(Indiana Products Liability Act, Ind. Code §34-20, *et seq.*)**

39. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

40. At all relevant times, Biomet was responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and selling the M2a Magnum Hip System.

41. Biomet manufactured, supplied, and marketed the M2a Magnum Hip System. The M2a Magnum Hip System was defective and unreasonably dangerous in design or formulation. When the M2a Magnum Hip System left Biomet, the foreseeable risks of the product greatly exceeded the benefits associated with its design or formulation, it was more dangerous than an ordinary and reasonably prudent consumer would expect, and it failed to comply with federal requirements for these medical devices. The product was expected to, and did, reach Plaintiff without substantial change in the condition in which it was sold.

42. The M2a Magnum Hip System is defective in design because it uses cobalt chromium (CoCr) for the ball and the inside of its shell. The metal-on-metal design can lead to excessive release of metal particles into the blood, which causes patients unnecessary pain and other complications. The device's defects also cause premature loosening, necessitating repeat surgical procedures.

43. Defendants marketed and sold the M2a Magnum Hip System in its defective condition even though alternative products designed in a safe or safer manner were feasible and marketable at the time Defendants sold it to Plaintiff.

44. As a direct and proximate result of Plaintiff's use of the M2a Magnum Hip System, Plaintiff has suffered serious physical injuries, harm, damages, and economic loss in the future.

45. Plaintiff demands judgment against Defendants for compensatory and punitive damages, interest, costs of suit, attorneys' fees, and all other relief the Court deems proper.

**COUNT III**  
**PRODUCTS LIABILITY – FAILURE TO WARN**  
**(Indiana Products Liability Act, Ind. Code §34-20, *et seq.*)**

46. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

47. Biomet is the manufacturer, designer, distributor, seller, and/or supplier of orthopedic devices including the M2a Magnum Hip System.

48. Biomet's M2a Magnum Hip System was defective when it left Biomet. The M2a Magnum Hip System neither conformed to Biomet's representations concerning the product, nor conformed to applicable federal requirements. Biomet failed to warn of the defects, problems, risks, or hazards with its product. Biomet had a duty to warn of its product's potential harm because Biomet knew healthcare providers implanted these products in patients, and could this product could cause substantial physical harm and suffering when used in its normal and customary manner. Biomet breached its duty because its warning was inadequate, and that breach harmed Plaintiff.

49. Biomet distributed and sold the M2a Magnum Hip System in the same condition when it left its place of manufacture, in the original form of manufacture, and that condition included the described defects. Upon leaving Biomet, the M2a Magnum Hip System reached Plaintiff without substantial change or adjustment in its condition.

50. Plaintiff's healthcare provider implanted her with the M2a Magnum Hip System, and Plaintiff then used the M2a Magnum Hip System in its intended manner. Plaintiff suffered severe physical, emotional, and other injuries as a result.

51. The M2a Magnum Hip System was in a dangerous and defective condition, and posed a threat to any of its users or consumers.

52. The M2a Magnum Hip System is unreasonably dangerous because Defendants sold it to Plaintiff without adequate warnings regarding, *inter alia*, the defects described above.

53. Biomet knew or should have known through testing, adverse event reporting, or otherwise, that implantation of the M2a Magnum Hip System created a high risk of bodily injury and serious harm.

54. Defendants knew and had information confirming the defective and dangerous nature of the M2a Magnum Hip System. Despite this knowledge and information, Defendants neither adequately nor sufficiently warned Plaintiff and her physicians that M2a Magnum Hip System could cause serious injuries including release of metal ions into the bloodstream, loosening, and the need for revision surgery.

55. Plaintiff and her physician justifiably relied upon Biomet's warnings or lack thereof regarding the M2a Magnum Hip System when they selected this product for use in surgery.

56. Biomet's breach of its duty to warn of the dangers and risks regarding the character and quality of the M2a Magnum Hip System and the failure to comply with federal requirements caused Plaintiff harm upon use of the M2a Magnum Hip System. Plaintiff suffered serious physical injury, harm, damages, economic loss, and will continue to suffer in the future.

57. Plaintiff demands judgment against Defendants for compensatory and punitive damages, interest, costs of suit, attorneys' fees, and all other relief the Court deems proper.

**COUNT IV**  
**NEGLIGENCE**

58. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

59. At all relevant times, Biomet had a duty to exercise reasonable care in the design, manufacture, testing, inspection, labeling, promotion, marketing, and sale of the M2a Magnum Hip System to ensure that it would be safely used in a manner and for a purpose for which it was made.

60. Biomet breached this duty by failing to exercise ordinary care in the design, manufacture, testing, inspection, labeling, promotion, marketing, and sale of the M2a Magnum Hip System.

61. Biomet maliciously, recklessly, and negligently misrepresented the safety and effectiveness of the M2a Magnum Hip System to Plaintiff and Plaintiff's orthopedic surgeon. In reliance on these misrepresentations, Plaintiff's orthopedic surgeon decided to use the M2a Magnum Hip Implant in Plaintiff's surgeries. But for Biomet's misrepresentations, Plaintiff's orthopedic surgeon would not have used the M2a Magnum Hip System in Plaintiff's surgeries.

62. Biomet maliciously, recklessly, and negligently failed in its duty to exercise reasonable care in providing an adequate warning to Plaintiff and Plaintiff's physicians as to the risks of the M2a Magnum Hip System.

63. Biomet maliciously, recklessly, and negligently failed to exercise reasonable care in the post-marketing warnings as to the risks of the M2a Magnum Hip System when it knew or should have known of reported risks.

64. Plaintiff suffered the previously stated injuries and damages because of Biomet's wrongful conduct.

65. Plaintiff demands judgment against Defendants for compensatory damages, punitive damages, interest, costs of suit, attorneys' fees, and all other relief the Court deems proper.

**COUNT V**  
**BREACH OF EXPRESS WARRANTY**

66. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

67. At all relevant times, Biomet expressly warranted to Plaintiff and Plaintiff's physicians, that the M2a Magnum Hip System was safe, effective, fit, and proper for its intended use. Biomet, its authorized agents, or its sales representatives made these warranties created this express warranty through its written and oral statements. Those written statements included publications, package inserts, and other written materials intended for physicians, medical patients, and the public.

68. Biomet's warranties and representations were false because the M2a Magnum Hip System was not safe, and was unfit for its intended use.

69. In utilizing the M2a Magnum Hip System, Plaintiff and Plaintiff's physician relied on Biomet's skill, judgment, representations, and express warranties. But for Biomet's misrepresentations, Plaintiff's orthopedic surgeon would not have used the M2a Magnum Hip System in Plaintiff's surgeries.

70. Because of Biomet's breach of express warranties, Plaintiff suffered injuries and damages as alleged in this complaint.

71. Plaintiff demands judgment against Defendants for compensatory damages, punitive damages, interest, costs of suit, attorneys' fees, and all other relief the Court deems proper.

**COUNT VI**  
**BREACH OF IMPLIED WARRANTY**

72. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

73. Prior to Plaintiff using the M2a Magnum Hip System, Biomet impliedly warranted to Plaintiff and Plaintiff's physicians that the M2a Magnum Hip System was of merchantable quality, was safe, and was fit for its intended use.

74. Plaintiff and Plaintiff's physician reasonably relied on Biomet's skill, judgment, and implied warranties in selecting and using the M2a Magnum Hip System.

75. The M2a Magnum Hip System was neither safe for its intended use nor of merchantable quality, Biomet warranted. The M2a Magnum Hip System had dangerous propensities when put to its intended use, and would cause severe injuries to the user.

76. By selling, delivering, and distributing the defective M2a Magnum Hip System to Plaintiff, Biomet breached the implied warranty of merchantability and fitness for a particular



purpose. This breach caused Plaintiff to, inter alia, suffer severe pain, emotional distress, incur medical expenses, and incur a loss of earning capacity.

77. Because of Biomet's breach of implied warranty, Plaintiff suffered the above injuries and damages.

78. Plaintiff demands judgment against Defendants for compensatory damages, punitive damages, interest, costs of suit, attorneys' fees, and all other relief the Court deems proper.

### **COUNT VII** **FRAUD**

79. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

80. On or about 2005, Plaintiff became a candidate for hip replacement surgery. Given Plaintiff's activity level and age, her doctor, Dr. Parsley, contacted Biomet. On information and belief, Biomet represented that the Biomet M2a Magnum hip implant was the best option for her based on her age, her history as an Olympic gold medalist athlete, and her current activity level. Plaintiff reasonably relied on this information from Biomet, agreed to have the hip replacement surgery, and then suffered injury. These representations by Biomet were false.

81. As early as 2006, Defendants made false statements of past or existing material fact directly to Plaintiff. After her first hip implant, Biomet advised Plaintiff, on multiple occasions, that Biomet's product releases less metal ions, and therefor is safe to use, i.e. the metal released is not harmful. Defendants' false or misleading statements include, but are not limited to:

- Not disclosing to Plaintiff the risk of loosening of the M2a Magnum Hip System,

- Not disclosing to Plaintiff the risk of the release of metal ions into the blood stream in amounts harmful to humans,
- Not disclosing that the release of metal ions (specifically chromium and cobalt) from the M2a Magnum Hip System can cause, inter alia, tissue and bone death,
- Not disclosing that the damage caused by the M2a Magnum Hip System can necessitate additional hip surgeries for repair, revision, or replacement of their M2a Magnum Hip System,
- And, by affirmatively stating to Plaintiff that their M2a Magnum Hip System releases significantly less metal ions than other hip implants.

82. Defendants knew these affirmative statements were false, because as early as 2006, the FDA received complaints about the product. Despite those FDA complaints, Defendants knowingly failed to disclose the aforementioned facts. Between 2006 and 2013, Biomet continued to give false or misleading information to Plaintiff about the safety and efficacy of their M2a Hip Systems. Despite the existence of more than 80 complaints about it submitted to the FDA in 2011 alone, Defendants touted the safety and efficacy of the device, specifically the drastically reduced rate of metallic ion release with the M2a Magnum System. Because of Biomet's indoctrination with propaganda regarding its line of metal-on-metal hip implants, Plaintiff ultimately elected to have her right hip implanted with one of Biomet's systems in 2011. The FDA MAUDE database received more than 500 complaints about Biomet's M2a Magnum Hip System from 2004 to the present, a number of these related to metal debris coming off the hip system and injuring the consumer. To date, Biomet still fails to provide warnings about the aforementioned issues to Plaintiff and others.

83. These statements and failures to disclose were material in nature because Plaintiff relied on these statements in selecting her 2011 hip implant. From 2006-2011, Defendants misrepresented the M2a Magnum Hip System to Plaintiff to as being safer than comparable products since it releases far fewer metal ions, as being safe, and as being effective for use in hip repairs requiring total hip replacement. In 2011, Plaintiff underwent an additional hip replacement surgery on her right hip, and utilized Biomet's implant again, due largely to her interactions with Biomet. Specifically, at trade shows and other such events, between 2006 and 2013, Defendants placed a small and a large pile of metal shavings in front of the M2a Magnum Hip System and represented to Plaintiff that Biomet's hip implants released far fewer metal ions as opposed to competitor's hip implant systems.

84. Plaintiff justifiably acted upon Defendants' statements and omissions. She relied upon the information that she received, and got a second Biomet implant in 2011. She publicly touted the benefits of Biomet's M2a Magnum Hip System as being safe and releasing far fewer metal ions than other hip implants. The entire time, the M2a Magnum Hip System injured Plaintiff, unbeknownst to her, by the release of large amounts of metal ions, specifically chromium and cobalt, into her body. In 2013, Plaintiff experienced pain in her hips, in reliance on defendant, she was hesitant to seek medical or legal help, since she believed that her implants were safe. Plaintiff justifiably relied and acted upon Biomet's statements and omissions, and her actions were justified because she had no way of knowing about the release of metal ions into her system until she became ill and had diagnostic bloodwork performed on or about January 22, 2014. Plaintiff did not know, nor could she have known of the damage Defendants' product caused until her healthcare provider informed her of high levels of chromium and cobalt in her

blood on or about January 22, 2014. Her reliance on these and other of Biomet's representations were reasonable, and Plaintiff was damaged as a result.

85. Defendants' actions and inactions injured Plaintiff. Plaintiff's bloodwork from January 2014 onward evidenced the large release of metal ions into her body. Plaintiff needed a revision surgery on her left hip on or about June 29, 2015. Plaintiff experienced substantial pain and suffering in and around her pelvis and hip. During her June 2015 revision surgery, healthcare providers found fluid in and around Defendants' M2a Magnum Hip System. Plaintiff needs an additional revision surgery on her right hip. Plaintiff actively promoted Defendants' product as safe and effective to others who also were injured. Plaintiff touted the benefits of Defendants' product as being unlikely to cause the very injuries she suffered.

86. Defendants' M2a Magnum Hip System directly and proximately caused Plaintiff to suffer economically in being unable to work due to additional surgery, debilitating pain, and immobility from. Plaintiff could not participate in her family's activities because of the debilitating pain, immobility, and mental anguish she suffered resulting from using Defendants' M2a Magnum Hip System. Plaintiff will continue to suffer mentally, physically, and economically in the future due to injuries and damages from Defendants' M2a Magnum Hip System.

87. Plaintiff contends that Biomet's conduct rises to the level of oppression, fraud, malice, willfulness, wantonness, or with reckless or conscious disregard for human life and safety, to warrant the imposition of exemplary damages.

**COUNT VIII**  
**PUNITIVE DAMAGES**

88. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

89. Plaintiff is entitled to punitive damages because the Defendants' wrongful acts and omissions were wanton or in conscious disregard of the rights of others.

90. The Defendants misled both the medical community and the public at large, including Plaintiff, by making false representations about the safety and efficacy of the M2a Magnum Hip System. Defendants downplayed, understated, and disregarded their knowledge of the serious and permanent side effects and risks associated with the use of the M2a Magnum Hip System. Despite available information demonstrating that the M2a Magnum Hip System could cause, inter alia, release of metal ions into the body, loosening, pain and other serious harm to patients, Defendants continued to advertise otherwise.

91. Defendants could have easily avoided such risks and adverse effects had Defendants not concealed knowledge of the serious and permanent side effects and risks associated with the use of the M2a Magnum Hip System.

92. Defendants' misrepresentations included knowingly withholding material safety information of the M2a Magnum Hip System from the FDA, from the medical community, and from the public, including Plaintiff, concerning the safety.

93. Defendants were or should have been in possession of evidence demonstrating that the M2a Magnum Hip System caused serious side effects. Nevertheless, Defendants continued to market the M2a Magnum Hip System by providing false and misleading information with regard to its safety and efficacy.

94. Defendants failed to provide warnings that would have dissuaded health care professionals from using the M2a Magnum Hip System, thus preventing health care professionals and consumers, including Plaintiff, from weighing the true risks against the benefits of using the M2a Magnum Hip System.

95. Plaintiff contends that Biomet's conduct rises to the level of oppression, fraud, malice, willfulness, wantonness, or with reckless or conscious disregard for human life and safety, to warrant the imposition of punitive damages.

### **PRAYER**

Plaintiff respectfully prays that this court grant her all relief requested in this complaint, and any other relief that this court sees fit.

### **JURY DEMAND**

Plaintiff hereby demands a trial by jury as to all claims in this action.

Respectfully submitted,

Riley Williams & Piatt, LLC



William N. Riley (#14941-49)

Joseph Williams (#25874-49)

Hammond Block Building

301 Massachusetts Avenue

Indianapolis, Indiana 46204

(T) 317.633.5270

(F) 317.426.3348

Email: [wriley@rwp-law.com](mailto:wriley@rwp-law.com)

[jwilliams@rwp-law.com](mailto:jwilliams@rwp-law.com)

Of Counsel

David P. Matthews (*Pro hac to be filed*)

Texas Bar No. 13206200

MATTHEWS & ASSOCIATES

2905 Sackett St.

Houston, TX 77098

(T) 713.522.5250

(F) 713.535.7184

E-mail: dmatthews@matthewslawfirm.com

Joseph Osborne (*Pro hac to be filed*)

Florida Bar No.: 880043

OSBORNE & ASSOCIATES

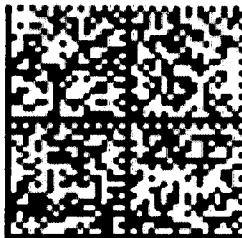

433 Plaza Real, Suite 271

Boca Raton, FL 33432

(561) 293-2600

(561) 923-8100

E-mail: josborne@oa-lawfirm.com

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